MCL 600.2912b AMENDED NOTICE OF INTENT TO FILE CLAIM

This Notice is intended to apply to the following health care professionals, entities, and/or facilities as well as their employees and/or agents, actual or ostensible, thereof, who were involved in the treatment of Robert Schroder.

John Chatas, M.D.
135 S. Prospect St.
Ypsilanti, MI 48198-7914

Painless Chelsea Services, LLC
c/o John Chatas
3520 Green St. Ste 100
Ann Arbor, MI 48105-1566

Ann Arbor Surgery Center, PLLC
c/o John Chatas
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Michigan Pain Specialists, PLLC
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Michigan Pain Specialists, P.C.
c/o John Chatas
15632 Troon Ct.
Northville, MI 48168-8477

Michigan Pain Specialists
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135 S. Prospect St.
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PROFESSIONAL CORPORATION AND ANY AND ALL PROFESSIONAL CORPORATIONS, AS WELL AS AGENTS, EMPLOYEES, ACTUAL OR OSTENSIBLE THEREOF

FACTUAL BASIS FOR CLAIM

Robert Schroder was referred to Michigan Pain Specialists where, intermittently, he received steroid injections for back pain. On September 25, 2012, Dr. John Chatas of Michigan Pain Specialists administered a steroid injection to Mr. Schroder. All treatment was provided at the Brighton clinic of Michigan Pain Specialists. Drs Chatas was an anesthesiologist who represented to Mr. Schroder that these injections would relieve his back pain. In addition to being an anesthesiologist, Drs. Chatas also had a Michigan dispensing license which effectively allowed him to act as a pharmacist. Mr. Schroder was not aware that Michigan Pain Specialists purchased their steroid injections in bulk from a compounding pharmacy in Massachusetts, the New England Compounding Company (hereinafter NECC). Neither Dr. Chatas nor anyone else at Michigan Pain Specialists informed him of this. He did not know that the law required pain clinics to provide patient specific prescriptions for steroid injections and required the compounding pharmacies to only supply such medication if it had patient specific prescriptions. Furthermore, Mr. Schroder did not know that bulk sales/purchases of this steroid from a compounding company were unlawful. Mr. Schroder was unaware that in December, 2006, the FDA had issued a warning letter to NECC regarding problems at their company with respect to the sale of compounded drugs without patient specific prescriptions, problems with storage and sterility and other problems. That warning letter has been posted on the FDA's website and was available for Michigan Pain Specialists and/or its physicians to review any time it wished. As a patient, following the advice of trained physicians, Robert Schroder believed that these injections were safe and not contaminated. The Michigan Pain Specialists and their physician Dr. John Chatas

represented to Robert Schroder that they would only administer medication which was prescribed for him and was safe, non-contaminated and designed to treat/cure his illness, not cause him to contract a deadly disease.

In September 2012, health officials identified an outbreak of fungal meningitis which was traced to the steroid injections compounded by NECC.

On/or about October 6, 2012, Mr. Schroder received a phone call from Michigan Pain Specialists advising him that he "may have gotten a contaminated shot." On October 8, 2012, Mr. Schroder received a call from Dr. Chatas informing him that he had definitely received an injection of the contaminated medicine. He was advised of the symptoms to watch out for including headaches, light sensitivity, dizziness, nausea, stiff neck and cognitive changes. Mr. Schroder had been experiencing these symptoms including headaches, neck pain and light sensitivity so he went to the Emergency Room at St. Josephs Hospital in Ypsilanti. On October 10, 2012, Mr. Schroder had a painful spinal tap performed. The results were inconclusive. Mr. Schroder continues to suffer anxiety and requires on-going monitoring for meningitis and/or abscess.

APPLICABLE STANDARD OF PRACTICE OR CARE ALLEGED

PHYSICIAN

The standard of care requires that a reasonable and prudent physician such as Dr. Chatas who was caring for a patient such as Robert Schroder would:

a. Be aware of the multiple problems discovered with compounding pharmacies and recognize that the drugs they provided were not FDA approved;

b. Recognize that because compounding pharmacies are not subject to the same regulations as drug manufacturers, the physicians had a duty to ensure that

drugs they purchased from these compounding pharmacies were safe for administration to patients;

c. Be aware of the serious risks of pharmacy compounding which had been brought to the health professionals' attention years prior to 2012 in hearings in the Senate and in prominent articles in the national media e.g. March 24, 2005 article in USA Today **"Safety Concerns Grow Over Pharmacy Mixed Drugs"**; FDA published article, May 2007, **"The Special Risks of Pharmacy Compounding"** ;

d. Recognize that the American Society of Anesthesiologists, the American Society of Health-System Pharmacies and other medical societies had published a joint report which highlighted the increased risks to patients who use drugs from compounding pharmacies including death. The report noted that several deaths had been associated with improperly sterilized compounded products;

e. Recognize that compounding pharmacies are only permitted to provide medication based upon patient specific prescriptions;

f. Refrain from administering a steroid injection from a compounding pharmacy unless it was certain that the medication had been prescribed and prepared for a specific patient and/or was prepared in a manner which would leave it un-contaminated;

g. Be aware that in May 2012, the CDC published a report regarding fungal infections arising from medications obtained from a compounding pharmacy;

h. Be aware of and follow Guidelines published by the American Society of Health System Pharmacists (ASHP) which warned of the risks of using compounded drugs and the need to carefully evaluate such drugs and pharmacies which were producing them;

i. Recognize that if compounding pharmacies were selling drugs at a greatly reduced price from that of manufacturers who are regulated by the FDA it was likely that the quality of these drugs was inferior to those manufactured by FDA regulated drug companies;

j. Fully evaluate the safety record of the compounding pharmacy it was purchasing drugs from including, investigating whether it had ever been subject to warnings or negative actions from any regulatory body, including the FDA;

k. Inform their patients that they were administering drugs which were not FDA approved and were not manufactured by an FDA regulated drug company but

rather were cheap substitutes provided by a compounding company which had never been evaluated for safety; and,

l. Be aware that the compounded drugs from NECC did not have preservatives and were thus at greater risk to develop bacterial or fungal growth and inform patients of this;

The standard of care required of the institutional entities Michigan Pain Specialists, PLLC et al are vicarious and are based on the standard of care set forth for the provider identified above in this section.

MICHIGAN PAIN SPECIALISTS, PLLC, ET AL

The standard of care of a reasonable clinic/corporation providing pain treatment requires that it:

a. Ensure that all medications administered to patients had a patient specific prescription;

b. Ensure that all drugs purchased from a compounding pharmacy were compounded in a safe manner so as to prevent contamination of the drugs being administered to the patients;

c. Evaluate the safety history and reputation of the compounding pharmacy they were purchasing drugs from including investigating NECC's regulatory history with the FDA and/or the Massachusetts Board of Registration in Pharmacy;

d. Determine whether NECC had a history of adverse events, complaints, and/or product liability suits before procuring spinal injection medications from them;

e. Maintain current awareness of the dangers of sterile compounding and recommended practices related to the acquisition and administration of compounded sterile products, particularly those that are preservative free and/or heed all prudent and recommended practices;

f. Refrain from purchasing compounded injectable steroids from an unaccredited compounding pharmacy;

g. Recognize that if a compounding pharmacy was selling drugs at a deeply discounted price as opposed to FDA regulated drug companies, there was increased risk regarding the quality of these drugs;

h. Conduct an adequate investigation of the compounding pharmacy to ensure that the drugs it was selling at a deep discount were of equal quality as those sold by FDA regulated manufacturers and/or implement policies and procedures that would prevent procurement of purportedly sterile injectable medications from an out-of state compounding pharmacy with deplorable sterility procedures, a checkered regulatory past, product recall problems, and a history of adverse events and product liability suits; and,

i. Submit bills which reasonably reflected the deeply discounted price it was paying for the bulk steroids it was injecting into patients.

MANNER IN WHICH IT IS CLAIMED THAT THE APPLICABLE STANDARD OF PRACTICE OR CARE WAS BREACHED

The physician failed to comply with the applicable standard of care in as much as he failed to:

a. Be aware of the multiple problems discovered with compounding pharmacies and recognize that the drugs they provided were not FDA approved;

b. Recognize that because compounding pharmacies are not subject to the same regulations as drug manufacturers, the physicians had a duty to ensure that drugs they purchased from these compounding pharmacies were safe for administration to patients;

c. Be aware of the serious risks of pharmacy compounding which had been brought to the health professionals' attention years prior to 2012 in hearings in the Senate and in prominent articles in the national media e.g. March 24, 2005 article in USA Today **"Safety Concerns Grow Over Pharmacy Mixed Drugs"**; FDA published article, May 2007, **"The Special Risks of Pharmacy Compounding"** ;

d. Recognize that the American Society of Anesthesiologists, the American Society of Health-System Pharmacies and other medical societies had published a joint report which highlighted the increased risks to patients who use drugs from compounding pharmacies including death. The report noted that several deaths had been associated with improperly sterilized compounded products;

e. Recognize that compounding pharmacies are only permitted to provide medication based upon patient specific prescriptions;

f. Refrain from administering a steroid injection from a compounding pharmacy unless he was certain that the medication had been prescribed and prepared for a specific patient and/or was prepared in a manner which would leave it un-contaminated;

g. Be aware that in May 2012, the CDC published a report regarding fungal infections arising from medications obtained from a compounding pharmacy;

h. Be aware of and follow Guidelines published by the American Society of Health System Pharmacists (ASHP) which warned of the risks of using compounded drugs and the need to carefully evaluate such drugs and pharmacies which were producing them;

i. Recognize that if compounding pharmacies were selling drugs at a greatly reduced price from that of manufacturers who are regulated by the FDA it was likely that the quality of these drugs was inferior to those manufactured by FDA regulated drug companies;

j. Fully evaluate the safety record of the compounding pharmacy he was purchasing drugs from including, investigating whether it had ever been subject to warnings or negative actions from any regulatory body, including the FDA;

k. Inform his patients that he was administering drugs which were not FDA approved and were not manufactured by an FDA regulated drug company but rather were cheap substitutes provided by a compounding company which had never been evaluated for safety; and,

l. Be aware that the compounded drugs from NECC did not have preservatives and were thus at greater risk to develop bacterial or fungal growth and inform patients of this.

The breach of the standard of care by the institutional entities, Michigan Pain Specialists, PLLC et al are vicarious and are the same as the breaches of the standard of care set forth for the provider identified above in this section.

MICHIGAN PAIN SPECIALISTS, PLLC, ET AL

The breach of the standard of care of a reasonable clinic/corporation providing pain treatment was that it failed to:

a. Ensure that all medications administered to patients had a patient specific prescription;

b. Ensure that all drugs purchased from a compounding pharmacy were compounded in a safe manner so as to prevent contamination of the drugs being administered to the patients;

c. Evaluate the safety history and reputation of the compounding pharmacy they were purchasing drugs from including investigating NECC's regulatory history with the FDA and/or the Massachusetts Board of Registration in Pharmacy;

d. Determine whether NECC had a history of adverse events, complaints, and/or product liability suits before procuring spinal injection medications from them;

e. Maintain current awareness of the dangers of sterile compounding and recommended practices related to the acquisition and administration of compounded sterile products, particularly those that are preservative free and/or heed all prudent and recommended practices;

f. Refrain from purchasing compounded injectable steroids from an unaccredited compounding pharmacy;

g. Recognize that if a compounding pharmacy was selling drugs at a deeply discounted price as opposed to FDA regulated drug companies, there was increased risk regarding the quality of these drugs;

h. Conduct an adequate investigation of the compounding pharmacy to ensure that the drugs it was selling at a deep discount were of equal quality as those sold by FDA regulated manufacturers and/or implement policies and procedures that would prevent procurement of purportedly sterile injectable medications from an out-of state compounding pharmacy with deplorable sterility procedures, a checkered regulatory past, product recall problems, and a history of adverse events and product liability suits; and,

i. Submit bills which reasonably reflected the deeply discounted price it was paying for the bulk steroids it was injecting into patients.

THE ACTION THAT SHOULD HAVE BEEN TAKEN TO ACHIEVE COMPLIANCE WITH THE STANDARD OF PRACTICE OR CARE

The physician failed to do what was described as required in Sections 2 and 3 above in breach of the standard of care. More specifically, he should have:

a. Been aware of the multiple problems discovered with compounding pharmacies and recognize that the drugs they provided were not FDA approved;

b. Recognized that because compounding pharmacies are not subject to the same regulations as drug manufacturers, he had a duty to ensure that drugs purchased from these compounding pharmacies were safe for administration to patients;

c. Been aware of the serious risks of pharmacy compounding which had been brought to the health professionals' attention years prior to 2012 in hearings in the Senate and in prominent articles in the national media e.g. March 24, 2005 article in USA Today **"Safety Concerns Grow Over Pharmacy Mixed Drugs"**; FDA published article, May 2007, **"The Special Risks of Pharmacy Compounding"** ;

d. Recognized that the American Society of Anesthesiologists, the American Society of Health-System Pharmacies and other medical societies had published a joint report which highlighted the increased risks to patients who use drugs from compounding pharmacies including death. The report noted that several deaths had been associated with improperly sterilized compounded products;

e. Recognized that compounding pharmacies are only permitted to provide medication based upon patient specific prescriptions;

f. Refrained from administering a steroid injection from a compounding pharmacy unless he was certain that the medication had been prescribed and prepared for a specific patient and/or was prepared in a manner which would leave it un-contaminated;

g. Been aware that in May 2012, the CDC published a report regarding fungal infections arising from medications obtained from a compounding pharmacy;

h. Been aware of and followed Guidelines published by the American Society of Health System Pharmacists (ASHP) which warned of the risks of using compounded drugs and the need to carefully evaluate such drugs and pharmacies which were producing them;

i. Recognized that if compounding pharmacies were selling drugs at a greatly reduced price from that of manufacturers who are regulated by the FDA it was likely that the quality of these drugs was inferior to those manufactured by FDA regulated drug companies;

j. Fully evaluated the safety record of the compounding pharmacy he was purchasing drugs from including, investigating whether it had ever been subject to warnings or negative actions from any regulatory body, including the FDA;

k. Informed his patients that he was administering drugs which were not FDA approved and were not manufactured by an FDA regulated drug company but rather were cheap substitutes provided by a compounding company which had never been evaluated for safety; and,

l. Been aware that the compounded drugs from NECC did not have preservatives and were thus at greater risk to develop bacterial or fungal growth and informed patients of this.

Since the breach of the standard of care by the institutional entities, Michigan Pain Specialists, PLLC et al are vicarious the actions it should have taken are those set forth for the providers.

MICHIGAN PAIN SPECIALISTS, PLLC, ET AL

The actions the clinic/corporation should have taken in order to comply with the standard of care of a reasonable clinic/corporation providing pain treatment were it should have:

a. Made sure that all medications administered to patients had a patient specific prescription;

b. Made sure that all drugs purchased from a compounding pharmacy were compounded in a safe manner so as to prevent contamination of the drugs being administered to the patients;

c. Evaluated the safety history and reputation of the compounding pharmacy they were purchasing drugs from including investigating NECC's regulatory history with the FDA and/or the Massachusetts Board of Registration in Pharmacy;

d. Determined whether NECC had a history of adverse events, complaints, and/or product liability suits before procuring spinal injection medications from them;

e. Maintained current awareness of the dangers of sterile compounding and recommended practices related to the acquisition and administration of

compounded sterile products, particularly those that are preservative free and/or heed all prudent and recommended practices;

f. Refrained from purchasing compounded injectable steroids from an unaccredited compounding pharmacy;

g. Recognized that if a compounding pharmacy was selling drugs at a deeply discounted price as opposed to FDA regulated drug companies, there was increased risk regarding the quality of these drugs;

h. Conducted an adequate investigation of the compounding pharmacy to ensure that the drugs it was selling at a deep discount were of equal quality as those sold by FDA regulated manufacturers and/or implemented policies and procedures that would prevent procurement of purportedly sterile injectable medications from an out-of state compounding pharmacy with deplorable sterility procedures, a checkered regulatory past, product recall problems, and a history of adverse events and product liability suits; and,

i. Submitted bills which reasonably reflected the deeply discounted price it was paying for the bulk steroids it was injecting into patients.

THE MANNER IN WHICH THE BREACH WAS THE PROXIMATE CAUSE OF CLAIMED INJURY

Defendants' failure to recognize the significant risks associated with compounding pharmacies and specifically their failure to do any investigation whatsoever of the conditions, safety, or practices at NECC led them to purchase contaminated drugs which they then injected in Robert Schroder causing him to develop symptoms of fungal meningitis. Their failure to recognize that since NECC was selling them drugs in bulk at prices which were substantially lower than those charged by FDA regulated drug companies, the quality of these drugs was likely to be inferior to those sold by FDA regulated companies. Likewise, their purchase of these drugs in bulk should have led them to know the drugs were not being compounded based upon a patient specific prescription as required by Michigan law. As a result of their failure to act reasonably

when purchasing and administering drugs, Robert Schroder was administered a steroid injection which was contaminated with a fungus. He required painful diagnostic tests and, treatment with dangerous anti-fungal medication which can cause serious side effects. He continues to require monitoring.

NAME OF HEALTH PROFESSIONALS, ENTITIES AND FACILITIES NOTIFIED

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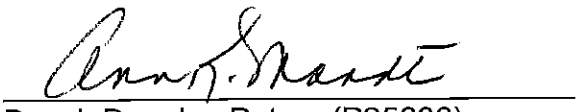
Professional Corporations and any and all employees and/or agents, actual or ostensible, thereof.

TO THOSE RECEIVING NOTICE: YOU SHOULD FURNISH THE NOTICE TO ANY PERSON, ENTITY, OR FACILITY NOT SPECIFICALLY NAMED HEREIN THAT YOU REASONABLY BELIEVE MIGHT BE ENCOMPASSED IN THIS CLAIM.

Respectfully Submitted,

CHARFOOS & CHRISTENSEN, P.C.



By: J. Douglas Peters (P25686)
Ann K. Mandt (P46314)
Attorneys for Plaintiff
5510 Woodward Avenue
Detroit, MI 48202
(313) 875-8080

DATED: October 11, 2013

PROOF OF SERVICE

The undersigned, being first duly sworn, deposes and says that on the 15th day of October, 2013, she served a copy of the **AMENDED NOTICE OF INTENT TO FILE CLAIM** by enclosing same in envelopes fully addressed to:

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135 S. Prospect St.
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with first class postage fully prepaid thereon and deposited same in the United States Mail in Detroit, Michigan.

CLAUDIA M. SIDDALL